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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,749	12/23/1999	JENNIFER L. HILLMAN	PF-0519-1DIV	7908

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	19

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/471,749	HILLMAN ET AL.	
	Examin r	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,24,25,27-30 and 41-45* is/are pending in the application.

4a) Of the above claim(s) *24,25,29,30,41 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,27,28 and 43-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *18* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Supplemental Final Action

1. Claims 21, 22, 24, 25, 27-30 and 41-45 are pending.

Claim 21 has been amended.

Claims 3, 6, 7, 9-12, 19, 20 and 23 have been canceled.

Claims 24, 25, 29, 30, 41 and 42, drawn to non-elected inventions are withdrawn from examination.

Claims 21, 22, 27, 28 and 43-45 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claims 21, 27, 28 and 43-45 under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants assert that the arguments presented in the previous Final Rejection mailed April 22, 2002 as Paper number 15 raised new issues and did not address the fragment claim

language, nor explicitly recite "fragments" in the 112, first paragraph rejection listed on page 2, paragraph 3 of Paper #15. The Examiner's response in regards to toxicology testing was solely in response to Applicants' arguments presented in Paper #14, received January 17, 2002. Furthermore, the role of fragments was encompassed by the previous 112, first paragraphs of record, see Paper 13, mailed September 7, 2001. The absence of the term "fragment" did not preclude it from the instant rejection as implied by Applicants. It is encompassed by the reference to "variants" including those comprising fragments.

Applicants argue that they discussed at length in Paper 10 received March 22, 2001 that there are a number of uses of the polypeptides of the present invention, which include toxicological screening, disease diagnosis and drug discovery. Moreover, Applicants assert that there is no requirement under the law to provide working examples of what is claimed and that the instant specification provides a requisite description of how to make and use what is claimed. This is found unpersuasive.

The Examiner has reviewed the entire specification and it is silent in regards to implementing molecules, SEQ ID NO: 3 and 5 in toxicological screening and drug discovery. The specification only contemplates the use of the said polypeptide sequences in disease diagnosis. And in that regard a legion of diseases are listed in the specification (page 32, lines 10-24) which according to the disclosure are capable of being remedied upon the administration of SEQ ID NO: 3 or 5. There is no corollary evidence presented that would substantiate treatment of inflammatory bowel disease or hepatoma with the same agents or that these disorders of differing pathology could be definitively diagnosed using the said molecules. Granted the Office does not require that experiments under the scope of the claims produce

positive and astonishing results, however the experiments must be within the scope of the Forman factors (see Ex parte Forman, 230 USPQ 546, BPAI, 1986). Applicants have not provided any objective evidence (neither *in vitro* or *in vivo)* or data that supports the use of SEQ ID NO: 3 and 5, also known HAPOP for toxicological screening, disease diagnosis or drug discovery. There are no assays of record demonstrating the treatment of subjects with any of the disorders listed on page 32.

Therefore, in weighing the factors to be considered in determining whether or not the practice of a claimed invention would require "undue" experimentation, as set forth in *In re Wands* (8 USPQ 2d at 1404), the weight of the analysis clearly favors a finding of "undue" experimentation.

4. The rejection of claims 21, 22, 27, 28 and 43-45 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicants aver the specification provides an adequate written description of the claimed "variants" of SEQ ID NO: 3 and 5. Additionally, Applicants assert that the present claims define the claimed genus through the recitation of chemical structure and do not define a genus, which is "highly variant". Applicants also argue that the state of the art at the time the claimed invention was made provides support that the inventors were in possession of the claimed variants at the time of the filing of the instant application. This is found unpersuasive.

The Examiner concurs with Applicants in the fact that naturally occurring molecules exists. The basis of this instant rejection is that Applicants were not in possession of the claimed variants. Applicants have not set forth evidence that supports their possession of all the variants that are claimed. Applicants have not identified the critical amino acids of SEQ ID NO: 3 or SEQ ID NO: 5 that can or cannot be altered or mutated and give rise to a polypeptide that is capable of functioning as a human apoptosis associated proteins. Applicants have not defined the boundaries of the genus. No correlation has been set forth between the structure of these variant proteins and the alleged function. For these reasons, as well as the rejections set before in Papers numbers 8, 9, 12 and 13 the rejection is maintained.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
October 10, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600